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Ken Sonnenfeld, Esq
Morgan & Finnegan LLP
345 Park Avenue
New York, NY 10154

EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/692,191	CIFRA ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-104* is/are pending in the application.

4a) Of the above claim(s) *2-23,30,31,36-67,73 and 76-98* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,24-29,32-35,68-72,74,75 and 99-104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-104 are presented for examination.

Acknowledgement is made of Applicant's claim for priority under 35 U.S.C. 119(e) to U.S. Provisional Patent Application Nos. 60/421,278, filed October 25, 2002 and 60/421,336, also filed October 25, 2002. Applicant's response filed January 6, 2006 to the requirement for restriction/election dated December 6, 2005 has been received and entered into the application. Accordingly, Applicant has also requested the entry and examination of newly added claims 99-104.

Requirement for Restriction/Election

Applicant's election **with traverse** of the invention of Group III (claims 24-35 and 68-75), drawn to a method for increasing elastin content in a tissue or in the eye, comprising the application of a composition of zinc-containing components topically or via placement of a contact lens in the eye, and the election **with traverse** of the species (xi), zinc citrate, as the species of zinc compound to be used, in the reply filed January 6, 2006, is acknowledged. Applicant's traversal is on the grounds that search and examination of the entire application can be made without serious burden to the Examiner, in particular, because each claim has been classified in the same class and subclass, i.e., class 424, subclasses 401 or 642.

Applicant's traversal has been carefully considered, but fails to establish error in the propriety of the present requirement for restriction and election.

Though Applicant asserts that examination of all pending claims would not pose an undue burden on the Examiner, such is not an accurate assertion in light of the disparate nature

of the presently claimed subject matter. First, the present claims are directed to multiple different and patentably distinct methods, such that the execution of one method would not necessarily encompass or result in the execution of any one of the other methods. In particular, the methods have been held to be patentably distinct because the patient populations in which each method would be practiced are distinctly different, such that the treatment of one patient population would not necessarily suggest, anticipate or render obvious the treatment of any one of the other patient populations. For example, patients requiring an increase in the amount of fatty tissue in or beneath the skin would most certainly not suggest the use of the same treatment in patients requiring a decrease in the amount of fatty tissue in or beneath the skin. The therapeutic objectives are sufficiently different such that the pathophysiological manifestations and etiology of each condition are distinct from one another, and the endpoints and steps required to execute any one of the methods are vastly different and do not reasonably suggest, anticipate or render obvious the execution of any one of the other methods. In light of the distinct nature of the various methods presently claimed, it is further noted that a comprehensive search for one method would not necessarily result in a comprehensive search of any one of the other methods and, thus, the claims are properly held to be drawn to multiple patentably distinct inventions and are, therefore, properly restricted.

In addition, Applicant presently claims a composition, which is known in the art for use in a wide variety of materially different processes, aside from those uses that Applicant has presently claimed, such as supplementation of subject's daily intake of zinc, for augmenting immune function, increasing absorption of zinc in vegetarians, and for the replacement of zinc during the course of acute digestive disorders, such as diarrhea, Crohn's disease or short bowel

syndrome. However, Applicant is reminded that compositions of matter are examined based upon their physical components and structural form, not the intended use of such a compound. In light of such, due to the variety of vastly different uses for the composition that are already known in the prior art, it is clear that a comprehensive search of the compound would necessarily entail a comprehensive search of the prior art well beyond simply those therapeutic methods that Applicant has claimed. As a result, an undue burden would be placed on the Examiner to examine all of the seven patentably distinct inventions presently claimed.

Given also that Applicant has presently claimed 56 different zinc compounds that may be employed in any one of the seven patentably distinct inventions of the present claims, such would give rise to, at minimum, 392 inventions. Regardless of the fact that they are all zinc-based, such does not change the fact that Applicant has claimed multiple patentably distinct inventions that are sufficiently different in operation, function, effect or resultant endpoint such that a comprehensive search for any one of these inventions would not necessarily result in a comprehensive search for any one of the other presently claimed inventions.

Consideration of the plurality of inventions that Applicant has claimed would significantly compromise and preclude a quality examination on the merits. Furthermore, execution of a search encompassing the entirety of Applicant's compounds and multiple therapeutic objectives would not only constitute an undue burden on the Examiner, but *consideration of the findings* of such a search in accordance with the requirements of the law under 35 U.S.C. §§101, 102, 103 and 112 would be unduly onerous.

Moreover, it is further noted that a comprehensive search for the presently claimed subject matter is not solely limited to a search of the class and subclass in which it is classified.

Therefore, it is obvious that a comprehensive search of the copious amounts of patent and non-patent literature for each of the seven patentably distinct inventions and the 392 permutations thereof of the presently claimed would *necessarily* place an undue burden on the Examiner.

Therefore, for the reasons above and those made of record at pages 2-8 of the previous Office Action dated December 6, 2005, the restriction requirement is deemed proper and is made **FINAL**.

Claims 2-23, 30-31, 36-67, 73 and 76-98 are **withdrawn** from further consideration pursuant to 37 C.F.R. 1.142(b), as being to non-elected inventions, there being no allowable generic or linking claim.

Applicant has newly presented claims 99-104 for examination. In light of the fact that each of claims 99-104 reads upon the subject matter elected for prosecution, such claims will be examined herein.

The claims corresponding to the elected subject matter are 1, 24-29, 32-35, 68-72, 74-75 and 99-104 and such claims are herein acted on the merits.

Applicant's Claim for Priority under 35 U.S.C. 119(e)

Applicant's claim for the benefit of two prior-filed applications under 35 U.S.C. 119(e) is acknowledged. Applicant is reminded that the later-filed application must be an application for patent for an invention that has been disclosed in the prior application (i.e., the provisional application(s)). The disclosure of the invention in the provisional application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32

USPQ2d 1077 (Fed. Cir. 1994).

The subject matter of claims 1, 24-29, 32-35, 68-72, 74-75 and 99-104 is considered to have sufficient support and enablement as required under 35 U.S.C. 112, first paragraph, in U.S. Provisional Patent Application No. 60/421,336, and is properly granted the effective filing date of this application (October 25, 2002).

Accordingly, for the purposes of examination and the application of prior art, claims 1, 24-29, 32-35, 68-72, 74-75 and 99-104 have been granted priority to October 25, 2002.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

I Claims 34-35 and 99-101 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The MPEP sets forth the following at §2173:

> "The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention." (See MPEP §2173).

The term "about" in the expression "from about 1.0 pM to about 900 μM" as recited in present claim 34, "from about 100 pM to about 500 μM" as recited in present claim 35, or "from about 1.0 pM to about 100 μM" as recited in present claim 99 is a relative term that renders the

claim indefinite. The expression "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The use of such a term would invite subjective interpretations of whether or not a particular dosage amount is included in or excluded from the present claims and what degree of variability outside the recited ranges is within the scope of the claims.

Furthermore, the Examiner also has noted the word "from" in present claims 34-35 and 99-101. For example, the word "from" in the phrase "from about 1.0 pM to about 900 μM" as recited in present claim 34, or ""from about 100 pM to about 500 μM" as recited in present claim 35, or "from about 1.0 pM to about 100 μM" as recited in present claim 99 indicates that the weight percent is between 1.0 pM to about 900 μM, 100 pM to about 500 μM or 1.0 pM to about 100 μM, respectively. However, the use of the word "about" denotes that the weight percent may be slightly greater or slightly less than 1.0 pM, for example, or 900 μM, for example. Thus, it is not clear which is meant to be the limiting term. It is the Examiner's position that the public would not be informed of the boundaries of what constitutes infringement of the present claims.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. §112, second paragraph and are, thus, properly rejected.

II Claims 68-72, 74-75 and 102-104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In particular, the phrase "providing in the vicinity of the lens one or more zinc-containing

components" as recited in present claim 68 is a phrase that renders the scope of the claim indefinite. Applicant has failed to delineate the area in which the zinc-containing components may be applied and still be considered "in the vicinity of" the lens. Absent any definition in either the present claims or the specification, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In fact, the use of such a term would invite subjective interpretations as to whether the location to which the zinc-containing components had been provided or applied would have been considered to be within the "vicinity" of the lens.

The MPEP directs at §2111, which states, "During patent examination, the pending claims must be given their broadest reasonable interpretation consistent with the specification." However, in the present case, the specification, nor the claims, provide any direction as to what would be considered to be inside or outside the vicinity of the lens. For these reasons, the term is given its broadest, reasonable interpretation. For example, it would not be outside the scope of the skilled artisan to interpret such a phrase to mean providing the zinc-containing components on or near the eyelid of the individual receiving such a therapy. However, an equally reasonable interpretation would be providing such zinc-containing components on or near the patient's mouth, which would result in a distinctly different therapeutic effect in treating disorders of the eye than when the components are provided directly to the eyelid. While such an embodiment of providing the components on or near the patient's mouth may not be what is intended to be claimed by Applicant, such is not precluded by the present claims, absent any direction to the contrary, because Applicant has not defined a range in which the components may be applied and still be considered "in the vicinity of" the lens. For these reasons, the metes and bounds of the claimed subject matter cannot be identified and, as a result, the public would not be informed

of the boundaries of what constitutes infringement of the present claims.

For the reasons given above, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 24-29, 32-35, 68-72, 74-75 and 99-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrus (U.S. Patent No. 6,573,299; Issued June 2003, Filed September 1999) in view of Riordan (U.S. Patent No. 5,866,142; 1999) and Ogle (U.S. Patent No. 6,113,636; 2000).

Petrus teaches a method for the treatment of orbital disorders associated with the aging eye, including the improvement of age-related changes to the eyelids, such as dry skin or wrinkles (col.2, lines 22-24; see present claims 1, 24-26, 68), by applying a topical composition comprising a penetration enhancer and one or more bio-affecting agents (col.2, lines 24-28), such as zinc citrate (col.13, lines 21-28, especially col.13, line 25; see present claims 1, 24-29, 32, 68-72, 100-101 and 103-104), wherein the bio-affecting agent penetrates the underlying tissue into the vascular network of the orbit via application to the eyelid surface (considered to meet Applicant's limitation of applying the composition to the face or the furrows or wrinkles of the face as recited in present claim 26 or in the vicinity of the lens as recited in present claim 68; see col.15, lines 31-32). Petrus further teaches that the composition may also include emollients (considered to meet Applicant's limitation of a "moisturizer" as recited in present claim 33; see col.14, lines 20-24), provided that the inclusion of such an additive does not defeat the objective of the invention (col.14, lines 34-35).

Regarding the use of the transitional phrase "consisting essentially of", the MPEP states at §2111.03, "The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention...For the purposes of searching for and applying prior art under 35 U.S.C. §102 and §103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising."

Applicant has failed to definitively point out the basic and novel characteristics of the invention. However, taken in its broadest, reasonable interpretation, the basic and novel

characteristic of the presently claimed invention must necessarily lie in the fact that the composition must retain efficacy in treating orbital disorders associated with the aging eye and improving age-related changes to the eyelids, such as dry skin or wrinkles.

If the composition must retain efficacy in treating orbital disorders associated with the aging eye and improving age-related changes to the eyelids, such as dry skin or wrinkles, in order to preserve the basic and novel characteristics of the invention, then the very fact that Applicant has claimed a composition "consisting essentially of one or more zinc-containing components in admixture with a dermatologically or pharmaceutically acceptable carrier" is necessarily met by the reference. The inclusion of a penetration enhancer suitable for pharmaceutical or dermatological use, in the sense that it is suitable for application directly to the skin of a subject, meets Applicant's limitation of a pharmaceutically or dermatologically acceptable carrier. Furthermore, the inclusion of such an enhancer does not alter the ability of the composition to treat orbital disorders of the aging eye or improving age-related changes to the eyelids, such as dry skin or wrinkles. In fact, absent factual evidence to the contrary, Petrus teaches that the inclusion of the penetration enhancer improves the perfusion of the bio-affecting agent (i.e., zinc citrate) into the skin. Thus, the very presence of the penetration agent would have potentiated the ability of zinc citrate to treat the age-related orbital disorders and improve age-related changes to the eyelids. Such preservation in function indicates that the claim does not patentably exclude the presence of the penetration enhancer taught by Petrus because the presence of such an agent does not alter the efficacy of the composition in treating age-related orbital disorders or improving age-related changes to the eyelids.

The differences between the Petrus reference and the presently claimed subject matter lies in that the reference fails to teach:

(i) the increase in elastin content of the tissue (see present claims 24 and 68);

(ii) the application of the zinc compound to the breasts, buttocks, neck, legs, arms, torso and furrows or wrinkles in the hands or neck (see present claim 26);

(iii) the application of the zinc compound directly to the eye via a contact lens coated in the zinc-compound (see present claim 74); or

(iv) the presently claimed effective amounts of zinc compound (see present claims 34-35, 68, 75, 99 and 102).

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because:

(i) Though Petrus does not expressly teach that topical application of the disclosed active composition increases elastin content in the tissue, the very fact that the composition is used for improvement of dry skin and wrinkles as occurs with aging raises the reasonable expectation that such a treatment would necessarily have an effect on the elasticity of the skin, since wrinkles due to aging were known to result from a loss of elastin.

In this regard, Riordan (U.S. Patent No. 5,866,142; 1999) is cited. Riordan teaches, "One of the mechanisms of the loss of elasticity in aging skin is through the loss of elastin, a human protein which is a major component in elastic fibers and provides the skin with much of its elastic qualities...When the elastin molecules break down, they are removed by endogenous

immune surveillance mechanisms and may not be replaced at the same rate, resulting in a net loss of elastin in the skin tissue. At the area at the lateral folds of the eyes, the forehead, and on the neck, the chronic net loss of elastin allows for the formation of wrinkles." (col.2, lines 18-34)

Thus, it would have been plainly apparent to one of ordinary skill in the art that the improvement of wrinkles, particularly those in the peri-orbital area (i.e., in and around the eye) by topical application of an active composition (i.e., in this case, a zinc containing composition) would be reasonably expected to promote an increased concentration of elastin content of the skin. In other words, the function of a composition in improving wrinkles in and around the eye that result from a loss of elastin during aging would have raised the reasonable expectation that the composition would have exerted its effect, at least to some degree, by increasing the elastin content of the affected wrinkled skin. In light of the fact that wrinkles were known to result from a loss of elastin and elasticity of the skin, a composition used to improve wrinkles would have been reasonably expected to effect such an improvement by restoring elasticity via increasing elastin, thereby ameliorating the loose, sagging and creased skin associated with wrinkles.

(ii) Though the teachings of Petrus are limited in the sense that the zinc composition comprising zinc citrate is taught for the treatment of orbital disorders and the improvement of dry skin and wrinkles associated with the aging eye and do not expressly teach the topical application of the composition to other areas of skin, the use of the disclosed active zinc composition would have also been reasonably expected to exert the same anti-aging effect, i.e., to improve dry skin and wrinkles associated with aging, on areas of skin other than the peri-orbital area. Petrus teaches that zinc has a tightening effect of sagging or loose skin and also teaches that zinc is virtually non-toxic (col.12, lines 44-53).

In light of such a teaching, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to employ the zinc citrate composition disclosed by Petrus for topical application to other areas of skin on the body, including, but not limited to, those presently claimed, such as the breasts, buttocks, neck, legs, arms, torso and furrows or wrinkles in the hands or neck. Such a person would have been motivated to do so for cosmetic purposes, since dry skin and wrinkles associated with aging and the loss of elastin and elasticity of the skin are not limited only to the face and eye region, but rather can be found all over the body. The skilled artisan would have reasonably expected that a composition known to have efficacy in treating wrinkles of the skin in and around the eyes would also have had the same or substantially similar efficacy in treating wrinkles of the skin on other parts of the body. Furthermore, the very fact that zinc was known to be virtually non-toxic would have further motivated the skilled artisan to employ such a composition for topical use in regions of the body other than the face, since there would have been a reasonable expectation that such a composition would have been capable of exerting its effect without causing any undue or adverse side effects.

(iii) Though Petrus teaches topical application of the zinc composition directly to the eyelid surface and the skin around the eye, so as to allow the active components to penetrate the skin and be absorbed into the vasculature underlying such areas of skin, application of such an active composition directly to the eye via a medical device would have been a method of administration well within the purview of the skilled artisan.

Despite the fact that the active composition may be administered to the eye skin to treat orbital disorders and wrinkles and dry skin in and around the eye due to aging, whereby the

composition penetrates the skin and is absorbed directly into the bloodstream, the bioavailability and potency of the composition and the size of the surface area to which it is applied may limit the administration of the optimum dosage amount necessary to treat the eye. For this reason, the skilled artisan would necessarily look to other methods of administration to optimize the amount(s) of active agents that are actually administered directly to the eye for treatment, particularly those methods that would provide an effective amount of the active agent and maintain such an amount in direct contact with the eye to maximize the administered effective dose.

In this regard, Ogle (U.S. Patent No. 6,113,636; 2000) is cited. Ogle teaches cutaneous medical devices, such as contact lenses (col.5, lines 30-51), which are amenable to coating with an antimicrobial metal compound, such as zinc (col.4, lines 11-21), and are biocompatible for contact with bodily fluids (see abstract, for example). Ogle further teaches that an advantage of such devices is that they reduce the incidence of infection associated with contacting a patient with such a biocompatible material (see abstract, for example).

In light of the knowledge that was generally available to the skilled artisan at the time of the invention, the use of a contact lens device coated in the active zinc composition would have been a method of administration well within the purview of the skilled artisan. Such a person would have been motivated to do so because the use of a contact lens coated with active zinc compound would have maximized the effective amount delivered directly to the eye; the lens would have maintained the effective amount in contact with the eye for a longer period of time than relying on penetration of the skin alone; and lenses coated in active zinc were biocompatible when in contact with bodily fluids, even those found in the eye. Furthermore, the use of a

contact lens coated in active zinc was also known to have additional antimicrobial properties, which would have provided an additional advantage over standard topical application to the skin surface.

(iv) Petrus expressly teaches, "The concentration of the bio-affecting agents in the composition can also vary greatly and will be dependent upon many factors, e.g., type, bioavailability, potency, surface area to which it is applied, composition used and the amount of the penetrating agent used." (col.6, lines 56-60)

It is obvious from the above teachings that Petrus expressly contemplates variation in the concentration of the active bio-affecting agent (i.e., zinc citrate), of which such a determination of the concentration of active agent was a matter well within the skill of the artisan at the time of the invention and would not have required undue experimentation or have been outside the realm of knowledge generally available of the skilled artisan.

The determination of the optimum concentration of the presently claimed active zinc compound (i.e., zinc citrate) would have been a matter well within the purview of one of ordinary skill in the art. Such a determination would also have been made in accordance with a variety of factors other than those expressly named by Petrus, including the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, the concentration(s) that would have actually been employed would have varied widely and, in the absence of

evidence to the contrary, the currently claimed specific concentration(s) are not seen to be inconsistent with those that would have been determined by the skilled artisan.

Applicant's attention is drawn to MPEP at §2144.05, which states, "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages...Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

Conclusion

Rejection of claims 1, 24-29, 32-35, 68-72, 74-75 and 99-104 is deemed proper.

Claims 2-23, 30-31, 36-67, 73 and 76-98 are **withdrawn** pursuant to 37 C.F.R. 1.142(b) as being drawn to non-elected subject matter.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie A. Royds
Patent Examiner
Art Unit 1614

February 10, 2006

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600